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10/089,229	07/18/2002	Jari Natunen	0933-0185P	2480

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,229

Applicant(s)

NATUNEN, JARI

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

Claims 1-18 are pending in application

#### ***Information Disclosure Statement***

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 6 and 10 respectively, the phrases "m is 1 to 100, preferably 1 to 10" (in claim 6), "n' is an integer 1 to 8 preferably 1 to 6" (in claim 10) renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced

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by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation m is 1 to 100 and the claim also recites preferably 1 to 10 which is the narrower statement of the range/limitation. Similarly claim 10 recites the broad recitation n' is the integer 1 to 8 and the claim also recites preferably 1 to 6 which is the narrower statement of the range/limitation.

Regarding claim 12, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson (US 6,077,695).

In claim 1, applicant claims oligosaccharides having a given formula "wherein ..... monosaccharide 1 is Glc, or GlcNAcyl ..... monosaccharide 2 is optionally fucosylated Glc or GlcNAc ..... n is 1 to 100 ..... p and k are 0 and m is 1, in which case X is H ....."

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Nilsson discloses applicant's oligosaccharide having the given formula wherein monosaccharide 1 is Glc (glucose) and monosaccharide 2 is a fucosylated GlcNAc (GlcNAcyl) and n is 1, p and k are 0, and m is 1, and X is H (col. 13, lines 56-57). Nilsson refers to this compound as compound IE which is  $\text{Glc}\beta 1-4(\text{Fuc}\alpha 1-3)\text{GlcNAc}$  (col. 13, lines 56-57).

Claims 7,13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (US 6,319,695 B1).

In claim 7, applicant claims "the oligosaccharides according to claim 1, characterized in that X is an aglycon group selected from lower alkyl or alkenyl group 1 to 7, or 2 to 7 carbons, respectively ....." Wong et al disclose, applicant's oligosaccharide according to claim 1, characterized in that X is an alkenyl aglycon group of 3 carbons (i.e. 2-propenyl) (see col. 35, scheme 17, compound 45). In this compound, monosaccharide 1 is Gal (galactose) and monosaccharide 2 is a fucosylated GlcNAc (GlcNAcyl) and n is 1, p and k are 0, and m is 1, and X is 2-propenyl.

In claim 13, applicant claims "A process for the preparation of the oligosaccharides according to claim 1, characterized in that a compound of the formula I wherein B is always H, is fucosylated with donor nucleotide sugar containing L-fucose, or an analogue thereof, in the presence of a fucosyl transferase enzyme, and the fucosylated saccharide so prepared is optionally recovered. Wong et al. disclose applicants process for the preparation of the oligosaccharides according to claim 1 (compound 45), characterized in that a compound of the formula I wherein B is always H (compound 41), is fucosylated with donor nucleotide sugar containing L-fucose (GDP-fucose or abbreviated GDP-fuc), in the presence of a fucosyl transferase enzyme (Fucosyltransferase, abbreviated Fuc'T) (see col. 35, lines 4-51 and scheme

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17; see also example 13, col. 64 line 57- col.65, line 13). Claim 14 is drawn to mammalian  $\alpha$  1-3 or  $\alpha$  1-3 /4 fucosyltransferase. Wong et al. use mammalian  $\alpha$  1-3 or  $\alpha$  1-3 /4 fucosyltransferase (example 13, col. 64 line 57- col.65, line 13). Claim 15 is drawn to a process according to claim13 or characterized in that chitooligosaccharide is used as the starting material. Wong et al. disclose applicant process according to claim13 or 14 characterized in that chitooligosaccharide (compound 41) is used as the starting material (see col. 35, lines 4-51 and scheme 17; see also example 13, col. 64 line 57- col.65, line 13). Claim 16 is drawn to a process according to claim13 characterized in that the donor nucleotide sugar containing L-fucose is GDP-L-fucose. Wong et al. disclose applicant process according to claim 13 characterized in that the donor nucleotide sugar is GDP-L-fucose. (see col. 35, lines 4-51 and scheme 17; see also example 13, col. 64 line 57- col.65, line 13). Claim 17 is drawn to a process according to claim 14 characterized in that the fucosyltransferase is human  $\alpha$  1-3/4 or  $\alpha$  1-3 /4 fucosyltransferase ..... Wong et al. disclose applicants process according to claim 14 characterized in that the fucosyltransferase is human  $\alpha$  1-3 /4 fucosyltransferase (col. 35, lines 4-51 and scheme 17; see also example 13, col. 64 line 57- col.65, line 13; see also col. 16, table 1, line 35-55).

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 5,8-12 and 18 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record provided the 112 rejections are overcome, and the claims are written in a form independent of a rejected claim. The present invention relates to oligosaccharides having a given formula or oligosaccharide containing compounds including N-acetylated oligosaccharides which are fucosylated and optionally covalently bound to a carrier

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molecule and a process for preparing said compounds. The very relevant prior art document (US 6,319,695) to this invention discloses oligosaccharides or oligosaccharide containing compounds including N-acetylated oligosaccharides which are fucosylated.

However, though the compounds of the present invention are similar to those claimed in the prior art document, they possess structural differences (including different monosacharides and substituents) that are unobvious to those of the prior art. In addition, the process of preparation are also unobvious to those of the prior art.


### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

July 7, 2003.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1800